

<b>Interview Summary</b>	Application No. 08/162,984	Applicant(s) BOUCHARD ET AL.	
	Examiner Cecilia Tsang	Art Unit 1625	

All participants (applicant, applicant's representative, PTO personnel):

(1) Cecilia Tsang. CTsey

(3) Charles Van Horn. CLEVH

(2) Tom Erving. TE<sup>2</sup>

(4) Le Pennec Magali. MLP

Date of Interview: 09 February 2006.

Type: a) ☐ Telephonic b) ☐ Video Conference  
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: PowerPoint presentation: Discussion of the one-way and two-way tests for ODP. A paper copy of presentation is provided to be part of the interview record..

Claim(s) discussed: All.

Identification of prior art discussed: Bisserr, USPN 6441026.

Agreement with respect to the claims f) ☒ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Agreement was reached that the genus, species and intermediate are separate inventions. With regard to the one-way or two-way test, examiner would review all the papers and make the final determination.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

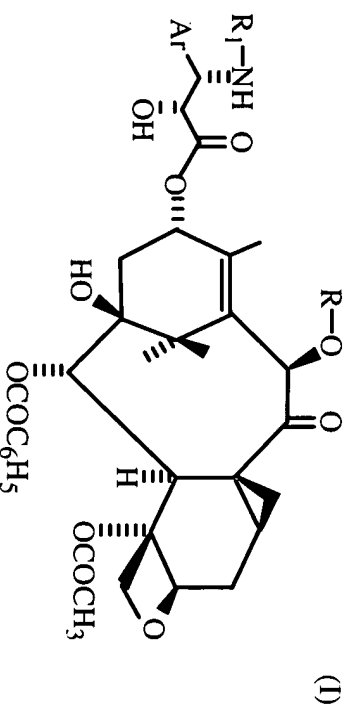
**U.S. Serial No. 08/162,984**

**In re Application of Bouchard et al.**

**Interview with Examiner C. Tsang**

**February 9, 2006**

- Claims 140-154 are currently pending
- **Genus Claim 140:**
  - A taxoid of the formula



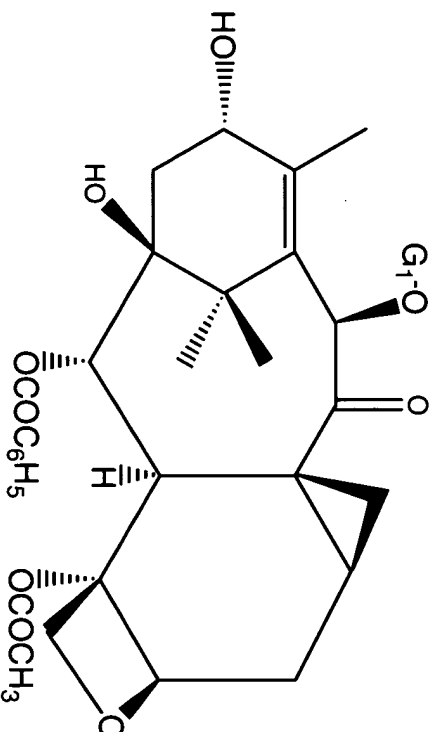
in which:

R represents hydrogen or acetyl,

R1 represents benzoyl or R2-O-CO- in which R2 represents t-butyl, and

Ar represents phenyl or  $\alpha$ - or  $\beta$ -naphthyl, said phenyl or naphthyl being unsubstituted or substituted by C1-4 alkyl, C1-4 alkoxy, halogen, or CF3, or Ar represents 2- or 3-thienyl or 2- or 3-furyl, said thienyl or furyl being unsubstituted or substituted by halogen.

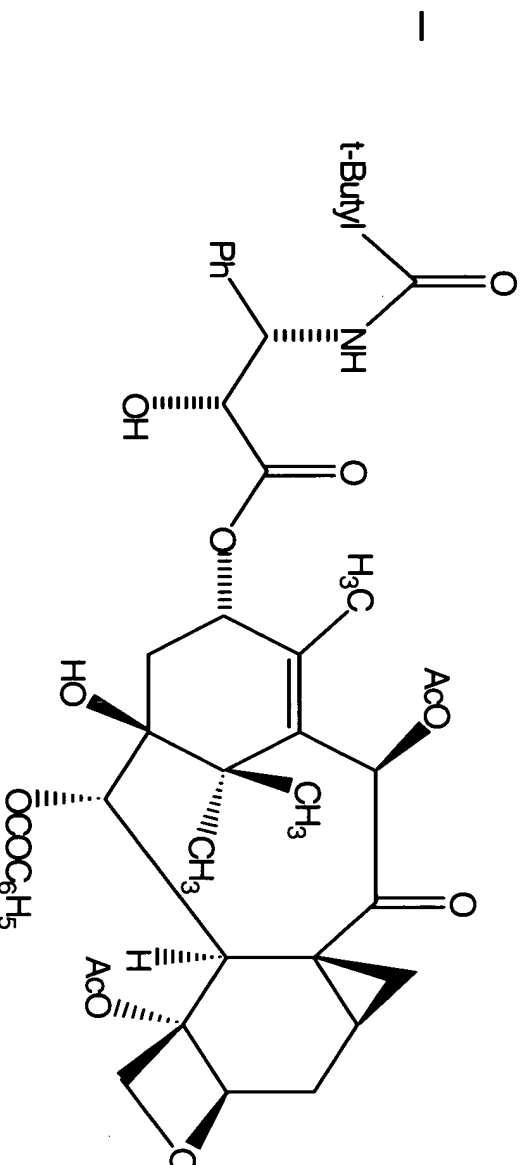
- **Intermediate Claim 141:**



in which G1 represents hydrogen or acetyl.

- **Species Claim 142:**

- 4 $\alpha$ -10 $\beta$ -diacetoxo-2 $\alpha$ -benzoyloxy-5 $\beta$ ,20-epoxy-1 $\beta$ -hydroxy-7 $\beta$ ,8 $\beta$ -methylene-9-oxo-19-nor-11-taxen-13 $\alpha$ -yl (2R,3S)-3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate.



## Timeline of Events

- Application filed December 8, 1993 (not refiled)
- Oct. 24, 1995 – Interference declared with 3 counts as *Chen v. Bouchard*, and assigned to APJ Mary Downey.
- Feb. 24, 1999 – Redeclaration of interference, adding third party, Hester.
- Jan. 31, 2000 – Order reformulating interference and adding two additional interferences, *Chen v. Hester* and *Hester v. Bouchard*.
- Dec. 4, 2000 – Interference transferred to Judge Andrew Metz.
- Aug. 2, 2002 – Board decision in favor of Bouchard on all counts.
- Oct. 22, 2003 – Federal Circuit affirms Board decision.

## Timeline of Events (cont'd)

- Since affirmance by the Federal Circuit in late 2003, the case was returned to prosecution, and the Examiner made an obviousness-type double patenting rejection on July 15, 2004.
- Ex. Trinh's May 11, 2005, Final Rejection:
  - Claims 140-154 rejected only for obviousness-type double patenting over claims 1-19 of U.S. Patent No. 6,441,026 to Bissery
  - “Although the conflicting claims are not identical, they are not patentably distinct from each other because the currently claimed cyclopropyl taxotere has been disclosed in [the] Bissery patent which is useful to treat a variety of cancer diseases, note compound in column 4 of the patent.” Office Action at 2.



U.S. Serial No. 08/162,984

Attorney Docket No. 03806.0046-00000

**(12) United States Patent**  
**Bissery**

(10) Patent No.: US 6,441,026 B1  
(45) Date of Patent: Aug. 27, 2002

**(54) ANTITUMOR COMPOSITIONS  
CONTAINING TAXANE DERIVATIVES**

**(TS)** Inventor: **Marie-Christine Bleszy, Vincy sur  
Seine (FR)**

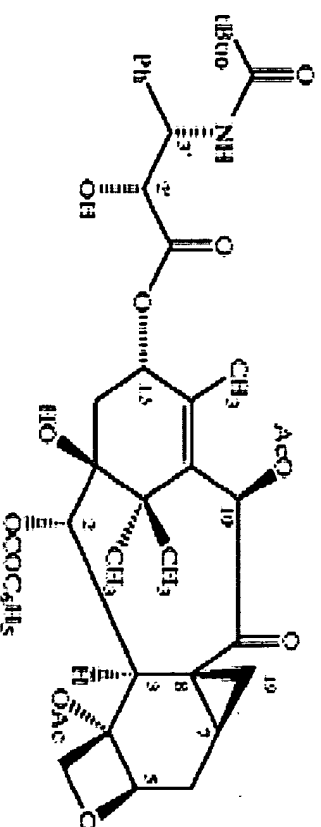
(73) Assignee: Aventis Pharma S.A., Anthony Cedex  
(FR)

(\*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/813,018

(22) Filed: Mar 21, 2011

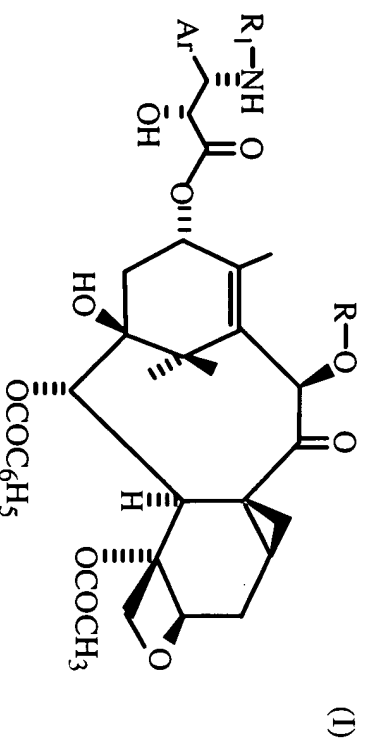
**What is claimed is:**  
1. A pharmaceutical composition comprised of the compound of formula 1:



or a derivative thereof, and at least one of an alkylating agent, an antimetabolite, a spindle poison, an epidophyllotoxin, an antibiotic, an enzyme, a topoisomerase inhibitor, a platinum coordination complex, a biological response modifier or a growth factor inhibitor.

## Genus Claim 140, Present Application

1. A taxoid of the formula:



in which

R represents hydrogen or acetyl,

R1 represents benzoyl or R2-O-CO- in

which R2 represents t-butyl, and

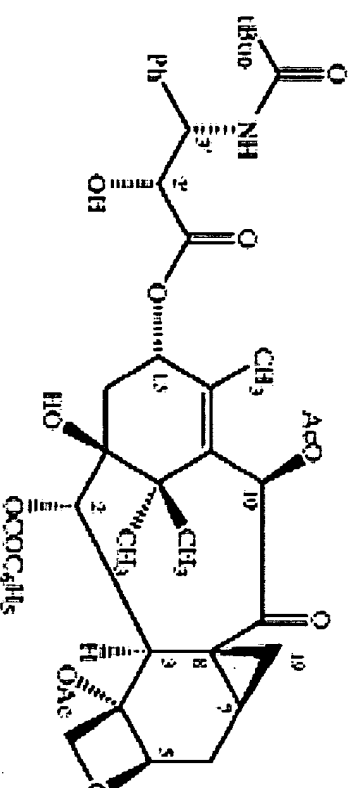
Ar represents phenyl or  $\alpha$ - or  $\beta$ -naphthyl,

said phenyl or naphthyl being unsubstituted or substituted by C<sub>1-4</sub> alkyl, C<sub>1-4</sub> alkoxy, halogen, or CF<sub>3</sub>, or Ar represents 2- or 3-thienyl or 2- or 3-furyl, said thienyl or furyl being unsubstituted or substituted by halogen.

## Combination Claim, Bissery '026

What is claimed is:

1. A pharmaceutical composition comprised of the compound of formula 1:



or a derivative thereof, and at least one of an alkylating agent, an antimetabolite, a spindle poison, an epipodophyllotoxin, an antibiotic, an enzyme, a topoisomerase inhibitor, a platinum coordination complex, a biological response modifier or a growth factor inhibitor.

- Bissery '026 only recites the species of claim 142 in combination with other anti-cancer therapeutics. There are no claims directed towards the genus of claim 140.

- The PTO has already held the genus of claim 140 and the intermediate of claim 141 to be separately patentable from the species of claim 142.

- In a memorandum to the Board, the Examiner found all three counts separately patentable.

- Note:
  - Count 1 = genus;
  - Count 2 = species;
  - Count 3 = intermediate

MEMORANDUM

DATE : August 10, 1995

TO : Board of Interference

FROM : Johann Richter, SPE 1201

SUBJECT: Initial Interference Memo re Appl.  
SN 08/162,984

Count 1 is directed to a Markush claim consisting of final products. It is therefore patentably distinct from count 3 which is directed to intermediate compounds used in preparing the final products.

Count 2, which is drawn to a species, is patentably distinct from count 1 because although embraced by the broad genus of count 1, applicants have provided data which demonstrates unexpected results, and hence, unobviousness over the broad genus of count 1. See the Declaration by Dr. Lavelle filed 4-27-95.

## THREE SEPARATELY PATENTABLE COUNTS


- The initial interference was declared on October 24, 1995, by APJ Mary Downey with three separate counts.
- Under the interference rules governing that interference, those three counts could exist only if they were separately patentable from each other. See 37 C.F.R. 1.601(f) (1993).

## THREE SEPARATELY PATENTABLE COUNTS

- Opponent Chen filed a motion challenging separate patentability of genus and species
- Chen withdrew the motion

DECISION ON PRELIMINARY MOTIONS  
Chen et al. motions 2

Chen et al. have withdrawn the motion and requests for discovery and testimony (Paper No. 52). Hence, the motion and requests are dismissed as moot.

  
Mary F. Downey  
Administrative Patent Judge  
(703) 308-9797

## CONCLUSION ON SEPARATE PATENTABILITY

- Examiner Johann Richter found the genus, intermediate, and species separately patentable. Aug 10, 1995, Memo.
- APJ Mary Downey found separate patentability by declaring the interference with three separate counts. See 37 CFR 1.601(f) (1993).
- APJ Andrew Metz never questioned separate patentability
  - “. . . this interference has three separate counts defining three separate inventions . . . .” Aug. 2, 2002, Final Board Decision at page 57.
- The Federal Circuit never questioned separate patentability
  - “There are three counts presently in this interference . . . .” *Chen v. Bouchard*, 347 F.3d 1299, 1302 (Fed. Cir. 2003).



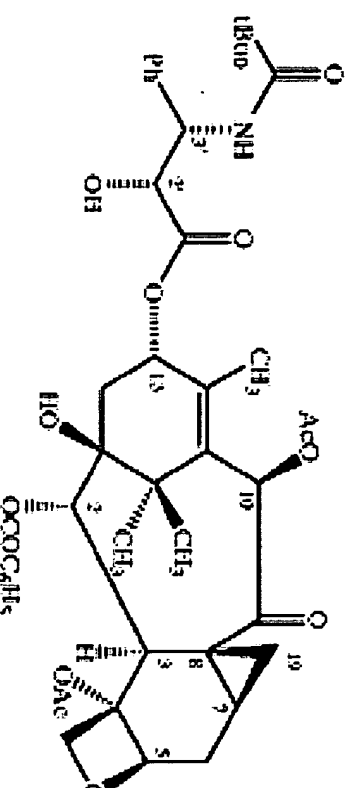
# SPECIES

## Species Claim 142, Present Application

142. 4 $\alpha$ -10 $\beta$ -diacetoxy-2 $\alpha$ -benzoyloxy-5 $\beta$ ,20-epoxy-1 $\beta$ -hydroxy-7 $\beta$ ,8 $\beta$ -methylene-9-oxo-19-nor-11-taxen-13 $\alpha$ -yl (2R,3S)-3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate.

## Combination Claim, Bissery '026

What is claimed is:  
1. A pharmaceutical composition comprised of the compound of formula 1:



or a derivative thereof, and at least one of an alkylating agent, an antimetabolite, a spindle poison, an epidophyllotoxin, an antibiotic, an enzyme, a topoisomerase inhibitor, a platinum coordination complex, a biological response modifier or a growth factor inhibitor.

## SPECIES

- **Question:** *Would the combination of the other anti-cancer therapeutics with the species (Bissery '026) have been obvious in view of the species (present application)?*

## SPECIES

- *As the claims of Bissery '026 are only directed towards the combination of the species together with other anti-cancer therapeutics, the claims of Bissery '026 would have been at most obvious to try in view of the species of claim 142.*

## SPECIES

- Dr. Bissery's Declaration explains possible outcomes of combination therapy:

➤ POSSIBLE OUTCOMES: No way to know a priori the combination result

- (1) Activity and Synergism
- (2) Activity and No Synergism
- (3) Antagonism in Activity
- (4) Antagonism and no activity
- Results 1 and 2 are desirable. Results 3 and 4 are undesirable.

# SPECIES

- Dr. Bissery's Declaration:  
(1) 5-FU

Product	Dose mg/kg/injection i.v.	Administration on days	Total Dose mg/kg	Log <sub>10</sub> cells killed
Taxotere	22	21, 25, 29, 33	88.0	1.4
5-fluorouracil	43.4	21, 25, 29, 33	173.6	1.1
Taxotere And	17.6	21, 25, 29, 33 (simultaneous)	70.4	4.8
5-fluorouracil	27.0		108.0	

Product	Dose mg/kg/injection i.v.	Administration on days	Total Dose mg/kg	Log <sub>10</sub> cells killed
Cyclopropyltaxane	40.3	14, 21	80.6	1.9
5-fluorouracil	90.0	14, 21	180.0	0.8
Cyclopropyltaxane And	18.8	14, 21 (simultaneous)	37.6	1.5
5-fluorouracil	67.5		135.0	

# SPECIES

- Dr. Bissery's Declaration:  
(2) Doxo

Product	Dose mg/kg/injection i.v.	Administration on days	Total Dose mg/kg	Log <sub>10</sub> cells killed
Taxotere	15	24, 27, 30	45.0	2.5
Doxorubicin	12.0	24	12.0	0.9
Taxotere And Doxorubicin	12.75	24	38.25	1.5
Doxorubicin	10.2		10.2	

Product	Dose mg/kg/injection i.v.	Administration on days	Total Dose mg/kg	Log <sub>10</sub> cells killed
Cyclopropyltaxane	34.0	15, 22	68.0	2.9
Doxorubicin	11.0	15, 22	22.0	3.0
Cyclopropyltaxane And Doxorubicin	34.0	15, 22 (Simultaneous)	68.0	5.3
Doxorubicin	11.0		22.0	

## CONCLUSION

- **Genus**
  - PTO has repeatedly concluded separate patentability of genus over the species recited in the Bissery claims
  - Accordingly, claims 140, 143, 145, 147, 149, 151, and 153 are patentable over Bissery '026
- **Intermediate**
  - PTO has repeatedly concluded separate patentability of intermediate over the species
  - Accordingly, claim 141 is patentable over Bissery '026

## CONCLUSION (Cont'd)

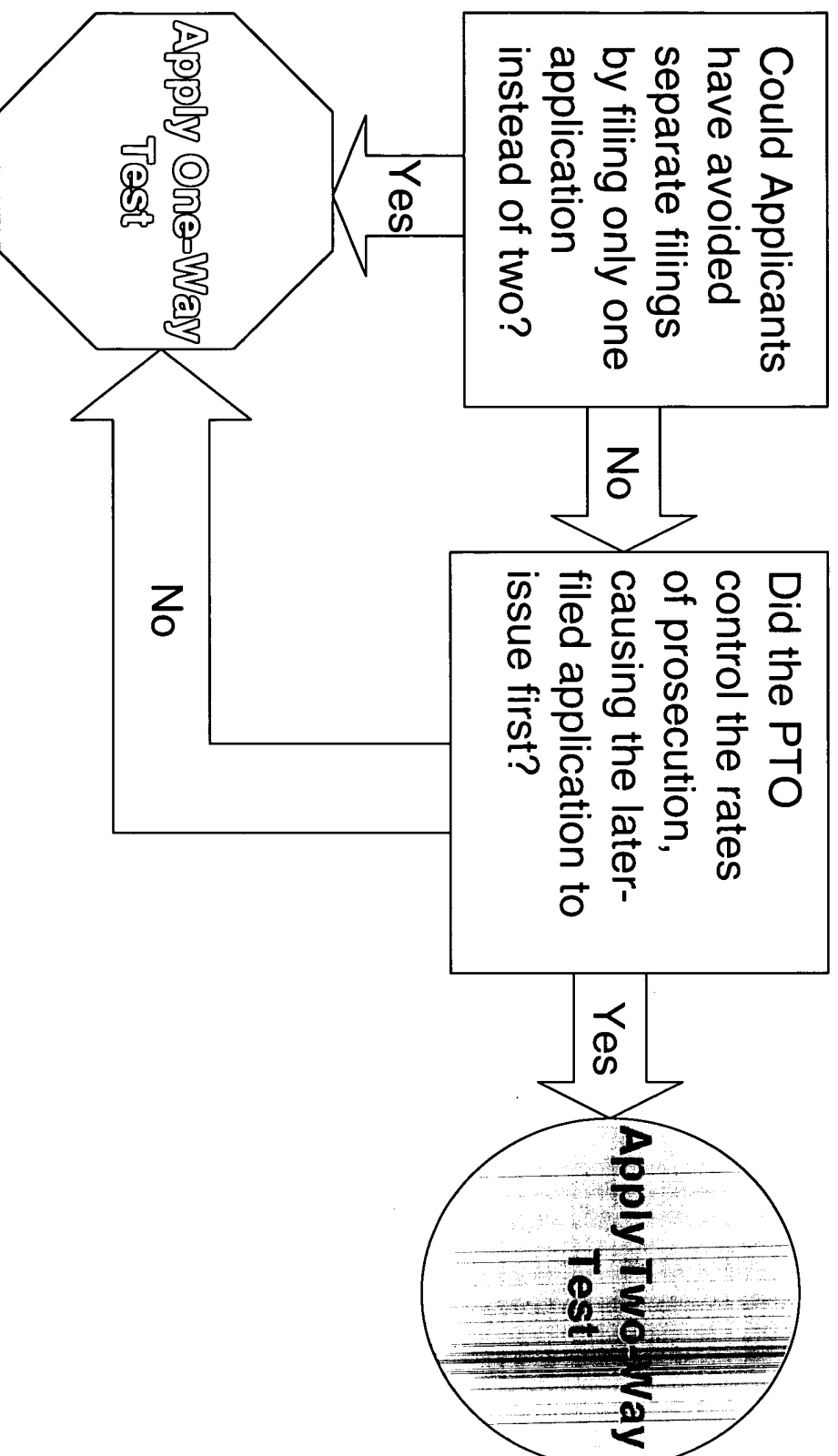
- **Species**
  - Separately patentable from Bissery '026 because at most obvious to try
  - Accordingly, claims 142, 144, 146, 148, 150, 152, and 154 are patentable over Bissery '026

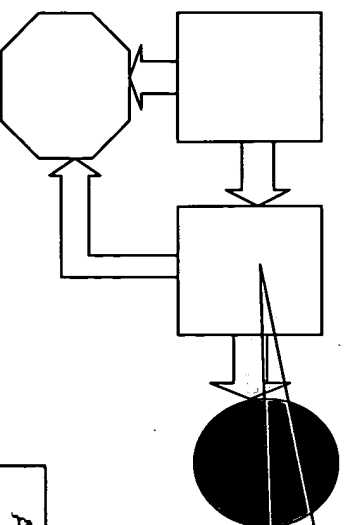


**U.S. Serial No. 08/162,984**  
**In re Application of Bouchard et al.**

**Discussion of the One-Way and  
Two-Way Tests for Obviousness-  
Type Double Patenting**

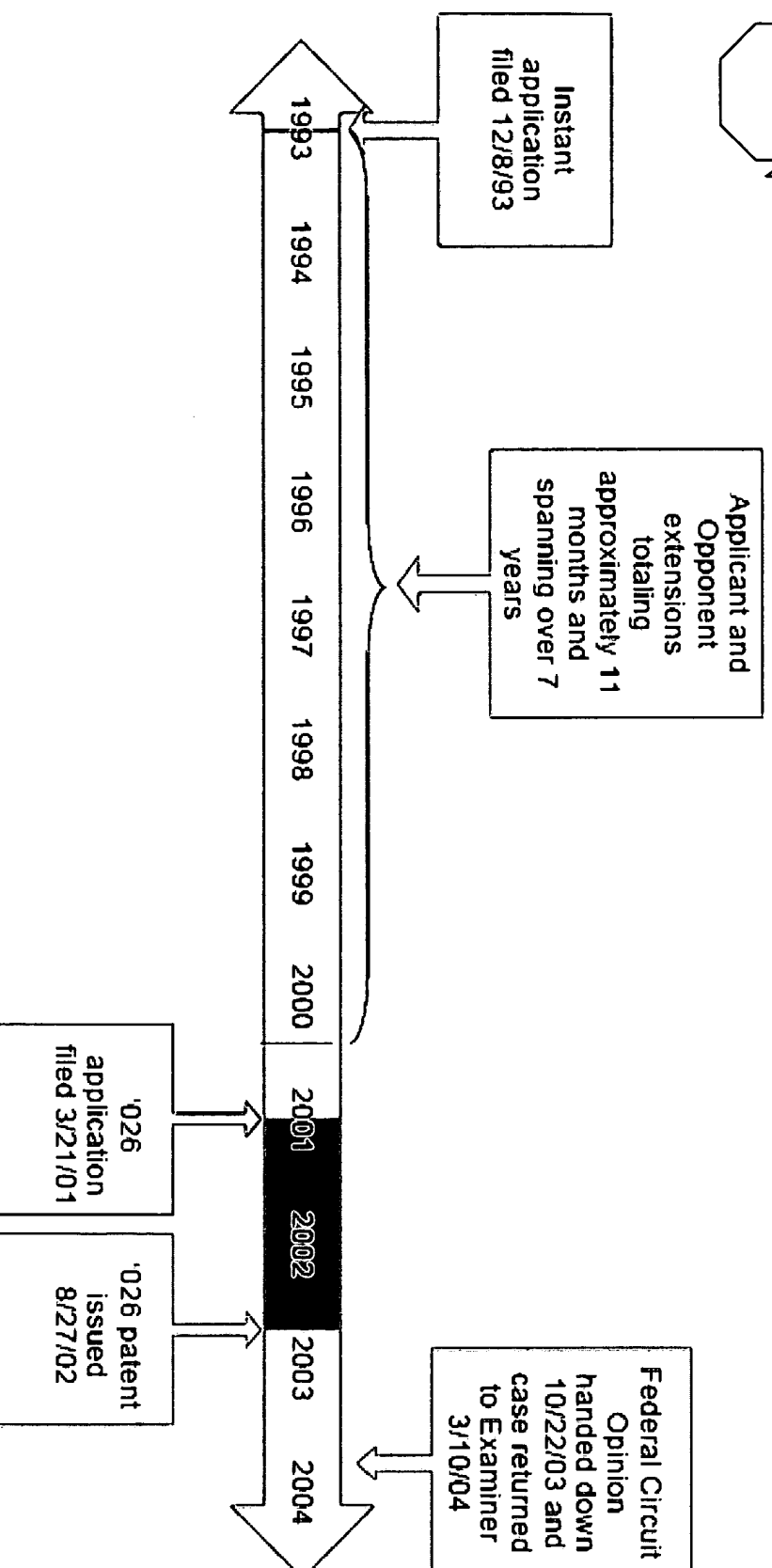
## When Should the Two-Way Test be Applied?

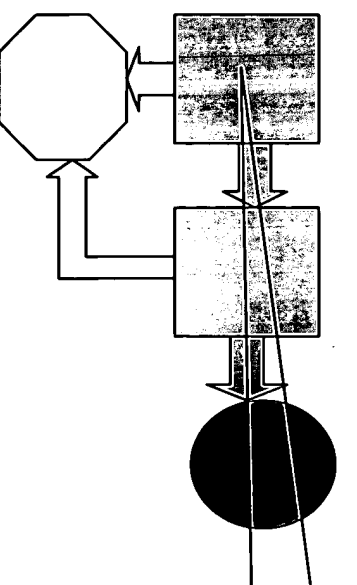




**Q: Did the PTO control the rates of prosecution, causing the later-filed application to issue first?**

**A: Yes.**

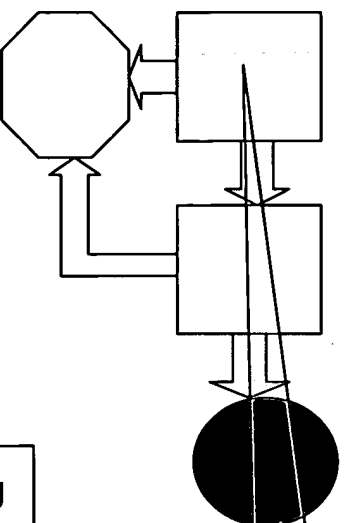




**Q: Could Applicants have avoided separate filings by filing only one application instead of two?**

**A: No**

- The '026 application was filed on March 21, 2001, significantly after the present application was filed, and reports work done subsequent to the 1992 and 1993 French and U.S. filing dates of the present application.
- Present Application broadly suggests combination therapy on pages 46-47 (See following slide). Actual testing, however, was not done until years later.



**Q: Could Applicants have avoided separate filings by filing only one application instead of two?**

**A: No**

**Pages 46-47 of the present application recite:**

**“The therapeutic treatment can be performed concurrently with other therapeutic treatments including antineoplastic drugs, monoclonal antibodies, immunotherapies or radiotherapies or biological response modifiers.”**

**Chemotherapeutic agents listed include alkylating agents, antimetabolites, epidophyllotoxins, antibiotics, enzymes, and coordination complexes of platinum, among others.**

- There is no support in the present application for all of the subject matter claimed in Bissery '026
- The instant application provides no written description support for the '026 patent claims as follows:
  - the **composition** as claimed in claims 1-9 of the '026 patent;
  - a **derivative** as claimed in claims 1-9 of the '026 patent;
  - **therapeutic synergy** as claimed in claims 10-19 of the '026 patent;
  - the class of **spindle poisons** as claimed in claim 1 (although species are disclosed); and
  - the class of **topoisomerase inhibitors** as claimed in claim 1.

## Therefore, the Two-Way Test Applies

